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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,445	08/01/2001	John L. Ricci	1065.34.1	4697

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EXAMINER
YOON, TAE H

ART UNIT	PAPER NUMBER
1714	

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Please find below and/or attached an Office communication concerning this application or proceeding.

A.S 3

Office Action Summary	Application No. 09/918,445	Applicant(s) Ricci et al
	Examiner T. Yoon	Group Art Unit 1714

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-41 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-5, 15-19, 29, 30 and 32-41 is/are rejected.

☒ Claim(s) 6-14, 20-28 and 41 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 16, 17, 29, 30, 32 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recited "derivatives" in claims 15, 16, 29 and 30 is indefinite in not specifying particular substituents or functional groups.

The recited "DTE" in claims 15 and 29 is indefinite and a full chemical spelling is needed in the at least first occurrence.

The recited "The method of claim 6" in claim 17 lacks an antecedent basis.

The recited "types" in claims 32 and 41 is indefinite. It is unclear what additional species are allowed into the genus of the terminology modified by "type". The word "type" therefore makes the modified terminology indefinite. See Ex parte Copenhaver, POBA, 1955, 109 USPQ 118-119.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) 1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a); or

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 5, 18 and 19 are rejected under 35 U.S.C. 102(e) as anticipated by Petersen (US 2002/0110541).

Petersen teaches a bone graft substitute composition comprising calcium sulfate hemihydrate, carboxymethylcellulose and sterile water and its use at [0021] and [0022] and in claim 16, 17 and 22.

Thus, the instant invention lacks novelty.

Claims 1, 4, 5, 18, 19, 33-37, 39 and 40 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Petersen (US 2002/0110541).

The separate packing of water and instruction sheet are inherent characters since the addition of water is only needed for an application (not during the storage) and since Petersen teaches various ratios of formulations.

Thus, the instant invention lacks novelty.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norton et al (US 5,681,873) alone, or in view of Ricci et al (US 6,224,635), Gerhart et al (US 5,085,861) or Petersen (US 2002/0110541).

Any polymeric particle containing a calcium sulfate meets the instant composition comprising a calcium sulfate compound and a polymer containing particle absent further limitation since said calcium sulfate compound can be a part of said polymer containing particle.

Norton et al teach a composition comprising a bioresorable polymer and a crystallization controlling agent in abstract. Various crystallization controlling agents such as a calcium sulfate (col. 4, line 44) and various forms such a sphere (col. 6, lines 8-10) are taught. Said composition

is expected to have the instantly recited resorption properties since the same components and applications are used.

Ricci et al (col. 1, lines 5-15), Gerhart et al (col. 6, line 50) and Petersen (col. 2, lines 1-2) teach various forms of calcium sufates including a calcium sulfate hemihydrate.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize a calcium sulfate in Norton et al since choosing a specie from the list is a *prima facie* obviousness, or further to utilize a calcium sulfate hemihydrate with teaching of Ricci et al, Gerhart et al or Petersen in Norton et al since the use of said calcium sulfate hemihydrate in bio applications is a routine practice in the art.

Claims 1-5, 18, 19, 33-36 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper et al (US 5,747,390) alone, or in view of Ricci et al (US 6,224,635), Gerhart et al (US 5,085,861) or Petersen (US 2002/0110541)..

Any polymeric particle containing a calcium sulfate meets the instant composition comprising a calcium sulfate compound and a polymer containing particle absent further limitation since said calcium sulfate compound can be a part of said polymer containing particle.

Cooper et al teach a composition comprising a bioabsorable/resorable polymer and a calcium containing filler at col. 2, lines 23-67. Particles comprising a calcium sulfate compound and a polymer are taught at col. 6, lines 8-21. Claim 1 shows implants coated with said particles. Said composition is expected to have the instantly recited resorption properties since the same

components and applications are used. The separate packing of water and instruction sheet are inherent characters since the addition of water is only needed for an application (not during the storage).

The instant invention recites a calcium sulfate and a calcium sulfate hemihydrate over Cooper et al. However, the recited formula of Cooper et al encompasses a calcium sulfate and Ricci et al (col. 1, lines 5-15), Gerhart et al (col. 6, line 50) and Petersen (col. 2, lines 1-2) teach various forms of calcium sufates including a calcium sulfate hemihydrate.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize a calcium sulfate in Cooper et al since choosing a specie from the list is a *prima facie* obviousness, or further to utilize a calcium sulfate hemihydrate with teaching of Ricci et al, Gerhart et al or Petersen in Cooper et al since the use of said calcium sulfate hemihydrate in bio applications is a routine practice in the art.

Claims 6-14, 20-28 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 15-17, 29, 30, 32 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,048,521 to Kohn et al teach poly(DTE carbonates) in examples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tae H. Yoon whose telephone number is (703) 308-2389. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan, can be reached on (703) 306-2777. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

THY/May 2, 2003

TAE H. YOON
PRIMARY EXAMINER